IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 017227/0138

In re patent application of
Barry L. REED *et al.*

Serial No. 09/125,436 Group Art Unit: 1616

Filed: December 18, 1998 Examiner: M. Williamson

For: DERMAL PENETRATION ENHANCERS AND DRUG DELIVERY SYSTEMS INVOLVING SAME

DECLARATION UNDER 37 CFR § 1.132
OF TIMOTHY M. MORGAN

Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Timothy M. Morgan, declare and state as follows:

I am a resident of 2/80 Keeley Lane, Carlton North Victoria 3054 Australia.

I am a qualified pharmacist, have completed a Ph.D. in Pharmaceutics (Victorian College of Pharmacy, Monash University), and have previously worked for Glaxo Australia, and currently work for a transdermal drug delivery company in Australia (Acrux Ltd).

I am one of the inventors of the above-referenced patent application.

I have read the Official Action mailed September 12, 2000 and I understand the Examiner's position, in particular on page 4 of the Official Action regarding factual showings with regard to the drying times of EP 522 405.

In order to demonstrate that the dermal composition of EP 522 405 A1 (Lintec) fails to meet the claimed limitation of a drying time of 3 minutes or less, the following experiments were either carried out by me personally or under my direct supervision.

Experimental Protocol

1. As set forth on page 8, lines 31-36, Example 1, Lintec specifies a 50% aqueous ethanol vehicle with 1% indomethacin and 1% anthranilic acid derivative as an enhancer. Accordingly, a dermal vehicle of 50% aqueous ethanol, 1% indomethacin and 1% enhancer (octyl salicylate) was formulated. Octyl salicylate was used instead of the closest anthranilic acid derivative, n-octyl anthranilate, because n-octyl anthranilate is not readily commercially available. However, the difference between these permeation enhancers would not be expected to effect the drying time of the dermal composition of Lintec's Example 1, particularly at a concentration of 1%.

2. For *in vitro* trying time measurements, 10 μL of each formulation was placed on a clean glass slide at room temperature on a 4 place analytical balance (0.0000g).

3. The time taken for the vehicle to stop evaporating at room temp (20°C) was measured.

4. This was repeated three times. The average trying time was 535 seconds (6 minutes, 55 seconds).

5. For *in vivo* drying time measurements, the experiments were repeated using volar forearm (32°C) of three subjects.

6. Formulation drying time was measured by visual verification (ie. no visible surface vehicle and or shine). The average drying time was 297 seconds (4 minutes, 57 seconds).

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As is clearly evident from the drying time, the composition of Lintec has a drying time that is significantly greater than the within 3 minute drying time now claimed in claim 11.

I further declare that all statements made in this declaration of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 30TH Jan 2001

Timothy M. Morgan